Regulatory Guide 10.8.2

Instructions for the Preparation of Applications for the use of Teletherapy Devices

Contents of an Application

The following paragraphs explain the information needed to evaluate license applications for the use of high intensity gamma radiation sources in teletherapy devices for treatment of humans.

Item 1. The applicant should list the full names of all individuals who will use or supervise the use of the teletherapy unit. This list should include the physicians who will actually use the teletherapy unit or direct the use of the unit by technologists or other paramedical personnel, or who will supervise physicians-in-training in a program of training in therapeutic radiology. Nonphysicians may be unauthorized to use the teletherapy unit for non-human use (e.g., instrument calibration).

Authorized physician-users have the following responsibilities:

A. Examination of the patient and his or her medical records to determine if radiation therapy is appropriate.

B. Prescription of the radiation dose and how it is to be administered (e.g., 5,000 rads to be delivered at the rate of 200 rads per day under specified conditions of field size, distance, angle, etc.).

C. Regular review of the patient's progress and modification of the originally prescribed dose as warranted by the patient's reaction to the radiation.

D. Actual use of, or direction of technologists or other paramedical personnel in the use of, the teletherapy unit.

E. Provision of necessary follow-up medical care.

Item 2. The applicant must specify whether the teletherapy source will be for human use only or for other additional uses.

Item 3. Instrumentation. The applicant should describe the instrumentation that is available for the teletherapy program. Such instrumentation must include the following:

A. A portable high-range survey meter with a range of at least 1 R/hour on the licensee's premises.

B. A beam-on radiation monitor permanently mounted in the teletherapy room and equipped with backup battery power supply.

C. A dosimetry system if the facility performs its own full calibrations or spot checks as required by WAC 246-240-040 (2) and (3).

D. An instrument of sufficient sensitivity to count wipe samples if the facility will perform its own leak tests (a low level survey meter is not acceptable for this purpose).

Appendix A of this guide contains a form that maybe used to describe these instruments.

Item 4. Instrument Calibration.

A. *Calibration of Beam-On Monitor*

While no calibration procedures specifically apply to beam-on monitors, the applicant should describe the procedures for ensuring that the monitor is operating properly. These procedures should be performed daily and may be incorporated in the procedures for other checks.

B. *Calibration of Dosimetry Systems*

For dosimetry systems used for teletherapy calibration or spot checks, WAC 246-240-040 (3) required that these systems be calibrated every two years by the National Institute of Standards and Technology or by a regional calibration laboratory accredited by the American Association of Physicists in Medicine. Alternatively, systems used solely for spot checks may be calibrated by a direct intercomparison with a system calibrated by the aforementioned calibration services.

Item 5. Facilities and Equipment. The applicant must provide a detailed description of the facilities and equipment of the teletherapy installation. Such description should include the following:

A. Annotated plan and elevation drawings or sketches of the teletherapy room and its surroundings showing:

1. The scale to which the drawings are made (the applicant should use the same scale for all drawings; recommended scale is 1/4 inch = 1 foot.

2. The direction of north.

3. The location of the teletherapy unit and source within the room.

4. The type, thickness, and density of shielding materials used on all sides of the room, including floor and ceiling.

5. The location of entrance, windows, conduits, and other penetrations and voids in the shielding materials.

6. The nature of, and distances to all areas adjacent to, above, and below the treatment room (plan and elevation drawings are particularly helpful in showing the relationship between the teletherapy facility and the roof and rest of the building.

7. The type of use of all areas adjoining the treatment room, including those above and below (areas should be specified as restricted or unrestricted as defined in WAC 246-220-060).

8. The height of earth against outside walls, if applicable.

B. Description of the systems that will be used to view and communicate continuously with the patient. If a shielded viewing window is used, the applicant should specify the thickness, density, and type of material. If electronic means are used to view or communicate with the patient (e.g., TV monitor, intercom), the applicant should specify the backup system that will be used in the event the system malfunctions or should confirm that patient treatment will be suspended until the systems are repaired and functioning again.

C. Description of area security safeguards (e.g., locks, signs, warning lights and alarms, and interlocking systems) for each teletherapy treatment room and the method of controlling occupancy of all **restricted** areas. Each door leading into the teletherapy room must be provided with an interlock to control the "on-off" mechanism of the teletherapy unit. The interlock must cause the source to move to the "off" condition if the door is opened when the source is exposed. The mechanism must be so wired that the source cannot be returned to the "on" condition until the door is closed and the system is reset at the control.

   If other radiation-producing equipment (e.g., linear accelerator, x-ray machine) is located in the teletherapy room, the applicant must describe the steps that will be taken to ensure that no two units can be operated simultaneously. The applicant's Department of Health Radiation-Producing Machine Registration Number and expiration date must be specified.

Item 6. Beam Stops. It may be necessary to restrict use of the teletherapy unit's primary beam because the treatment room walls, ceiling, or floor will not adequately shield adjacent areas from direct or scattered radiation. Electrical, mechanical, or other physical means (rather than administrative controls) must be used to limit movement or rotation of the unit.

The applicant should specify the mechanical or electrical beam stops that are operational and restrict beam orientation, the direction in which the teletherapy head can be moved, and the maximum angle (from vertical) of the beam orientation in each direction. The applicant should identify the angle orientation convention (e.g., 0^{o} is vertical toward the floor; 90^{o} horizontal toward the east wall; 180^{o}, vertical toward the ceiling; and 270^{o} horizontal toward the west wall). If the teletherapy unit has in integral beam absorber (beam catcher), the applicant should provide similar information for those orientations in which (a) the primary beam is directed **toward** the integral beam absorber and (b) the primary beam is directed **away from** the integral beam absorber. The applicant may use sketches to describe beam stops that limit the use of the primary beam.

Item 7. Shielding Evaluation. The facility must be designed so that the levels of radiation in any unrestricted area (as defined in WAC 246-220-010) adjacent to the facility meet the requirements of WAC 246-221-060. This paragraph requires that radiation levels in unrestricted areas be such that a person in the area will not receive a radiation dose exceeding either 2 millirems in any one hour or 100 millirems in any seven consecutive days if the person were continuously present in the area.

To demonstrate compliance with this regulation, the applicant should submit calculations of the maximum radiation levels that will exist in each restricted and unrestricted area adjacent to and above and below the shielded facility. These calculations should clearly indicate all parameters used in the calculations and should consider contributions from primary, leakage, and scattered radiation. These parameters will include beam orientation, maximum field size, scatter angles, scatter ratios, distance to scatterer, distances to areas of concern, type of material and thickness of barrier, attenuation factor of the barrier, etc. The calculations should show maximum radiation levels to be expected in any one hour and in any one week. In this regard, the applicant should give anticipated workload data (e.g., maximum number of patients treated per hour and per week, treatment time per patient, "on time" per hour and per week, average dose per patient). It should be noted that continuous occupancy must be used in making these calculations. The applicant should refer to Appendix B for a discussion of restricted and unrestricted areas, and submit information indicated in Section 2, Appendix B for each restricted area.

If the beam absorber is not used for all treatment, radiation levels must be calculated on the basis of an unattenuated primary beam where appropriate.

Calculated radiation levels in each area adjacent to the teletherapy room, including those above and below, should be indicated on a supplementary sheet keyed to the drawings.

The applicant should be aware that the Radioactive Materials License will require surveys and tests to be made prior to initiation of treatment and

following any changes made in the use of the teletherapy unit or the treatment room that could result in increased radiation levels outside the room. The results of these surveys and tests must be reported in writing to the department within 30 days after installation of the source or any changes. Appendix C describes minimum information and measurements that must be included in the report to meet these license conditions.

Item 8. Operating and Emergency Procedures. The applicant must describe the operating procedures that will be followed by teletherapy personnel. Appendix D describes items and procedures that should be included.

In addition, the applicant must submit a copy of emergency procedures to be followed in the event of a malfunction of a teletherapy unit. Appendix D describes an acceptable emergency procedure and may be referenced.

Item 9. Qualified Expert. If the individual who will perform the full calibration of the teletherapy unit does not meet the qualifications specified in WAC 246-240-040 (4), the applicant should provide a statement of the individual's training and experience for evaluation. This statement should include all of the information requested in Footnote 1, WAC 246-240-040.

Appendix A
Instrumentation

1. Survey Meters

a. Manufacturer's Name _____

Manufacturer's Model Number _____

Number of Instruments Available _____

Minimum Range _____ mr/hr to _____ mr/hr

Maximum Range _____ mr/hr to _____ mr/hr

b. Manufacturer's Name _____

Manufacturer's Model Number _____

Number of Instruments Available _____

Minimum Range _____ mr/hr to _____ mr/hr

Maximum Range _____ mr/hr to _____ mr/hr

2. Beam-On Monitor

Manufacturer's Name _____

Manufacturer's Model Number _____

Number of Instruments Available _____

Alarm set at _____ mr/hr

Backup Battery Power Supply ❑Yes ❑ No

3. Dosimetry System

a. Electrometer

Manufacturer's Name _____

Manufacturer's Model Number _____

b. Probes

Manufacturer's Name _____

Manufacturer's Model Number _____

Number of Probes _____

Ranges _____

4. Other

Appendix B *Unrestricted and Restricted Areas for Teletherapy Licensees.*

Each area adjacent to a teletherapy facility must be identified and maintained as either an unrestricted or a restricted area.

1. Unrestricted Area(s)

a. The standard teletherapy license condition requires that radiation levels in unrestricted areas meet the requirements of WAC 246-221-060 (1) (a) and (b). This section of the regulations requires that a person continuously present in an unrestricted area will not receive a dose exceeding 2 millirems in any one hour or 100 millirems in any seven consecutive days.

b. In showing compliance with WAC 246-221-060 (1) (a), the applicant:

   1. Must use an occupancy factor of unity because the regulation assumes that a person is continuously present, and

   2. May take advantage of "on-time" (i.e., that fraction of an hour or week during which the primary beam of radiation is on regardless of the orientation of the beam).

c. In showing compliance with paragraph WAC 246-221-060 (1) (a), the applicant may not use a fractional use factor, i.e., that fraction of the time during which the primary beam is directed at a particular barrier.

d. If appropriate records are maintained for inspection by the department, the applicant may use a fractional use factor to show compliance with WAC 246-221-060 (1) (b).

e. If compliance with WAC 246-221-060 (1) (a) and (b) cannot be demonstrated, the applicant has several options:

   1. Beam operation may be restricted (e.g., using electrical or mechanical stops) to limit the anticipated radiation level.

   2. Additional shielding may be added to the barrier in question.

   3. The applicant may designate and maintain the area as restricted, or

4. The applicant may request an exemption and demonstrate that the requirements of WAC 246-221-060 (2) are met. In this case, the applicant must include information on average radiation levels and anticipated occupancy times for each unrestricted area. The applicant must also maintain records to support the assumptions used in justifying the request for an exemption.

2. Restricted Areas

For each restricted area, the applicant must describe:

a. The physical and administrative controls used to restrict access to the restricted area.

b. The number, wording, size, and location of warning signs to be placed in the vicinity of the restricted area.

c. The program for ensuring that personnel entering the restricted area receive proper instruction in accordance with WAC 246-222-030.

d. The program for ensuring that personnel entering the restricted area are monitored in accordance with WAC 246-221-090.

e. The surveys that will be performed in accordance with WAC 246-221-110.

Appendix C *Teletherapy Survey Reports*

Standard license conditions for teletherapy licenses require the licensee to perform a radiation survey and to submit a survey report each time the teletherapy source is replaced or whenever any changes are made in the shielding, location, or use of the teletherapy installation which could affect radiation levels in surrounding areas.

The radiation survey must be conducted by a person who is: qualified by training and experience to measure ionizing radiation, to evaluate safety techniques, and to advise regarding protection needs; and who is knowledgeable and understanding of the operating characteristics, including the limitations of the radiation detection instrumentation and measuring devices that are used for the survey.

Contents of Survey Report

To fulfill the requirement for reporting the results of the radiation survey to the department, the survey report should:

a. Provide the name, address, and license number of the person or organization possessing the teletherapy unit and source.

b. Provide the names and addresses of persons conducting the survey.

c. Describe the reason for the survey (e.g., installation of a new source, relocation of unit).

d. Provide the date on which the work described in Item c was completed.

e. Provide the dates on which the survey was conducted.

f. Provide the following for each radiation detection instrument use for the survey measurements:

    1. The model number and manufacturer's name.

    2. The date of the last calibration prior to the instruments used in making these measurements.

    3. The standards (i.e., radionuclide, activity, and accuracy) and procedures used in the calibration.

g. Provide the model and serial number and manufacturer's name of the teletherapy unit.

h. Provide the model and serial numbers and the manufacturer's name of the teletherapy source.

i. Specify the activity of the source (in curies or becquerels) on the date of installation or the date of the survey.

j. Specify the intensity of the primary bean of radiation at a specified distance (e.g., RHM or RMM) as measured after the source has been installed in the head of the licensee's teletherapy unit and the date that this intensity was certified.

k. Provide the maximum and average radiation levels measured at one meter from the source in the "off" position. The average radiation level may be obtained by averaging measurements taken at 14 points on the surface of a sphere one meter in radius centered on the source. Up to 26 points may be measured in accordance with NCRP Report No. 33. Describe the locations of the 14 to 26 points and the radiation levels measured at each of the points.

l. Describe the limits of beam orientation permitted by electrical or mechanical stops installed on the teletherapy unit. Specify each direction in which the teletherapy head can be moved and the maximum angle (from the angel orientation (e.g., 0^{o} is vertical toward the floor; 90^{o} is horizontal toward the east wall; 180^{o} is vertical toward the ceiling; and 270^{o} is horizontal toward the west wall). The applicant may use sketches to describe the beam stops that limit the use of the primary beam.

   For units with an integral beam absorber, provide this information for orientations with the primary beam directed both toward and away from the integral beam absorber.

m. For measurements of radiation levels in adjacent areas, which should be made during irradiation of a phantom at the normal treatment distance using maximum field size:

   1. Indicate the direction of north.

   2. Show the location of the teletherapy unit and source within the room.

   3. Identify each area adjacent to the teletherapy facility (including above and below).

   4. Identify the locations at which radiation levels were measured (see Items o and p below).

n. Rotational Units:

1. For the primary beam directed toward the integral beam absorber, determine the rotational position of the teletherapy unit that causes the maximum radiation level in each area adjacent to the teletherapy facility (including above and below the facility). Report the maximum levels measured with a phantom in the primary beam and specify the corresponding rotational position (i.e., angulation toward each area). In general, maximum levels will be encountered with the beam oriented 30° from the perpendicular toward the barrier in question.

2. For the primary beam directed **away from** the integral beam absorber, report the maximum radiation levels measured in each area adjacent to the teletherapy facility (including above and below) and specify the orientation (i.e., angulation toward each area) which produces these maximum levels. Radiation measurements should be made with a phantom in the primary beam and with the beam in its most adverse orientation with respect to each barrier. In general, measurements should be made at the maximum limits permitted by the beam stops as described in Item 1.

o. For vertical units, report the maximum radiation levels that are measured in each area adjacent to the teletherapy facility (including above and below) and specify the orientations (i.e., angulation toward each area) which produce the maximum radiation levels. Radiation measurements should be made with a phantom in the primary beam and with the beam in its most adverse orientation with respect to each barrier. In general, measurements should be made at the maximum limits permitted by the beam stops described in Item 1.

p. For each measured radiation level reported in Items o. or p. that exceeds 2 milliroentgens per hour, explain how the licensee is complying with the regulations and the terms of the license. See Appendix B for further guidance.

q. Describe (1) the tests that were conducted and (2) the results of these tests that ensure proper operation of the safety systems described below: Note: **All tests must use a radiation detection instrument to confirm the "on-off" status of the source**.

1. Teletherapy treatment room door interlock. The test should be adequate to ensure that the door interlock operates in the manner described in WAC 246-240-030.

2. Teletherapy "on-off" indicators, both mechanical and electrical (e.g., lights on head of teletherapy unit, over door to room, at console).

3. Electrical or mechanical stops installed to limit use of the primary beam of radiation. The test should be adequate to ensure that beam stops operate in the manner described in Item 1.

4. Teletherapy treatment timing device. The tests should be sufficient to ensure that the timer is accurate, that the source returns to the "off" position at the end of the preset time, and that the source does not return to the "on" position until the timer is reset.

r. If a teletherapy unit or source was removed, provide:

1. The date of removal, and

2. The name, address, and license number of the person or firm who took possession os the unit or source.

s. If the surveyor recommends any changes to improve the safety of the operation of the teletherapy facility, describe the recommendations and the licensee's response to those recommendations.

Appendix D *Operating and Emergency Procedures*

1. Operating Procedures

Good health physics practice dictates that a licensee provide facility personnel with operating procedures to give them clear and specific directions for their duties and responsibilities. These duties may include safety device checks, instrument calibration, monthly spot checks, and leak testing. Operating procedures should not contain information that does not apply specifically to persons to whom they are directed. For example, housekeeping personnel would not follow the same procedures as therapy technicians.

The operating procedures should be designed to fit the program proposed in the application. Procedures should be complete and self-contained. Pertinent information contained in equipment manuals and other publications should be inserted into the operating procedures.

Topics that should be contained in the operating procedures include the following:

a. *Safety Device Checks.* Safety devices must be checked periodically to ensure that they are operating properly. Such devices include timers, mechanical and electrical interlocks, warning lights and alarms, safety switches, beam collimators, and other devices that actively warn of, limit, or prevent radiation exposure to either patients or personnel. The recommended frequency for safety device checks is at least once a week. A record of the results of the checks must be made. The operating procedures must include instructions for making the checks, the frequency with which they will be made, recording the results, and prompt correction of any malfunctions or defects noted. A simple checklist may be used to complete the task quickly and efficiently. When checks of safety devices indicate defects or malfunctions, there may be some delay before the defects or malfunctions can be corrected. The applicant should describe the procedures that personnel will follow should a delay occur. For example, use of the teletherapy unit might be forbidden until the problem is corrected, or alternate equivalent procedures such as requiring personnel to enter the room with an operable survey meter might be implemented.

b. *Personnel Dosimetry.* Operating procedures must require teletherapy personnel to wear personnel monitoring devices (film or TLD badges), and should contain instruction about the manner in which they should be worn. If pocket dosimeters will also be used, frequent readings should be required. The operating procedures must contain directions to be followed in the event that a person receives, or suspects that he or she has received, a high exposure. In this case, it

may be necessary for the dosimetry device of the affected person to be processed immediately. Procedures for storing the monitoring devices when not being worn should be in the operating procedures.

c. *Procedures for Securing Teletherapy Unit.* The operating procedures should specify the actions to be taken to ensure that the teletherapy unit is secure when unattended. Such actions should include locking the treatment room and the control panel, but may also include restricting access to the entire treatment area.

d. *Leak Testing*. If facility personnel will leak test sealed sources, specific instruction for performing the leak tests should be in the operating procedures. If the applicant uses commercially available leak-test kits, the instructions and procedures provided by the kit suppliers should be incorporated into the applicant's program.

e. *Recordkeeping*. Operating procedures must include instructions to be followed in the event of an emergency or unusual occurrence. The procedures should be clear and specific and should emphasize special features of the equipment or facility that may determine emergency action (e.g., using the main power disconnect to retract the source with possible cutting of power to room lights, gantry, or table controls). Limitations of action which may be taken by personnel should be specified. Normal procedures should limit action taken by teletherapy personnel to: quickly removing the patient from the room; securing or locking the room; and notifying proper persons. Emergency procedures must be posted at the control console of the teletherapy unit. Practice runs of these procedures should be performed after significant changes in personnel and periodically (e.g., semiannually) thereafter. Section 2 of this appendix contains an acceptable procedure.

f. *Procedures for Notifying Proper Persons in the Event of an Accident or Unusual Occurrence*. The operating procedures should specify the actions to be taken by facility personnel to notify appropriate persons in the event of an accident or unusual occurrence. The name and telephone numbers (both on and off duty) of at least two persons to be notified should be clearly indicated in the procedures. In addition, others, such as the hospital administrator, teletherapy manufacturer service representative and, in the case of a misadministration, the department, may require notification and should be indicated in the procedures.

2. Emergency Procedures in Case Beam Control Fails or Malfunctions

If the light signals or beam-on monitor indicate that the beam control mechanism has failed to terminate the exposure at the end of the preset time (e.g., if the red light stays on and the green light is off, or if both the

red and green lights stay on for more than a few seconds), the source may still be in the "on" position. The following procedure must be carried out promptly and in a calm manner:

a. **Turn off the main power switch at the control panel.**

b. If the patient is ambulatory, direct him or her to get off the table and leave the room.

c. Open the door to the treatment room.

d. If the patient is not ambulatory, enter the treatment room, but avoid exposure to the direct beam. Pull the treatment table as far away from the direct beam as possible. Transfer the patient to a stretcher and remove the patient from the room.

e. Close the door and secure the area by locking the door to the treatment room or posting a guard at the entrance.

f. Notify the radiation therapist and Radiation Safety Officer at once.

g. Post a conspicuous sign in the area to warn others of the problem.

Radiation Therapist _____

Phone No. — On Duty _____ Off Duty _____

Radiation Safety Officer _____

Phone No. _____ Off Duty _____